

**REMARKS/ARGUMENTS**

The FINAL Office Action dated June 15, 2006 has been reviewed and the comments have been considered. Claims 1, 5, and 10 have been amended. Accordingly, applicants request reconsideration, entry, and allowance of pending claims 1-12.

Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in the recitation of the areas of the surfaces recited in claims 1, 5, and 10. Applicants have amended claims 1, 5 and 10 to more particularly point out and distinctly claim the invention. In particular, applicants have amended claims 1, 5, and 10 pursuant to the Examiner's suggestion to delineate various portions or areas being claimed by reciting that a portion of the surface integral with the surface on which the reagent pad is affixed is a first surface (e.g., Figure 2) and the portion of the surface on which the reagent pad is affixed thereto (e.g., Figure 3) is a second surface. Support for the changes to the claims is shown and described in the originally filed application at page 3, lines 16-21, Figure 2 and page 3, lines 23-26, Figure 3.

Claims 1-3 and 10-11 stand rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by US Patent No. 6,299,838 to Hirayama et al., ("Hirayama"). Applicants respectfully traverse this rejection because Hirayama fails to show or describe each and every element of the claimed invention.

Each of claims 1 and 10 has been amended to place the application in condition for allowance. Specifically, claim 1 now recites a test device that includes, *inter alia*, a portion of a first surface—integral with a surface on which the reagent pad is affixed thereto and in direct contact with an aperture—has a reflectivity of less than about 12 percent at between about 600 and 730 nm. Claim 10 recites a system that includes, among other features, a first surface—integral with the surface of a support on which the reagent pad is affixed thereto and in direct contact with an aperture—has a reflectivity of less than about 12 percent at between about 600 and 730 nm.

In contrast, Hirayama fails to show or describe a surface integral with the surface on which the reagent pad is affixed thereto and in direct contact with an aperture has a reflectivity of any value or even less than 12% at a range from about 600 nanometers to about 730 nanometers.

In particular, Hirayama shows and describes, at column 5, lines 56-67, that support 1 is made of a different material (PET and thermoplastic resin) than a material of cover 5 (ABS resin). Furthermore, the reagent solution is coated to a light permeable porous film Nucleopore to form a reagent layer 3, which is attached to a surface of the support 1 rather than the cover 5. *See* Hirayama at col. 5, lines 49-55. It is submitted that no reflectance value or frequency range was given for the PET surface of support 1 on which the reagent pad 3 is attached thereto because Hirayama was concerned with the reflectance of a cover 5 located on a side of the reagent layer 3 opposite to the incident light (Hirayama at col. 2, lines 62-65 and col. 3, lines 1-3) rather than the reflectance of support 1.

Because Hirayama fails to show or describe the reflectance and frequency range for a specified area integral to the support 1 on which the reagent layer 3 is attached thereto, Hirayama fails to teach or suggest the claimed invention as a whole. Accordingly, claims 1 and 10 are patentable over Hirayama because Hirayama fails to teach or suggest each and every claimed feature.

Claims 3-9 and 11 stand rejected under 35 U.S.C. § 103 as being unpatentable over Hirayama in view of US Patent No. 5,843,692 to Phillips et al., ("Phillips"). Applicants respectfully traverse this rejection because Hirayama in view of Phillips fails to teach or suggest the claimed invention.

As amended, independent claim 5 recites a test device that includes, *inter alia*, a portion of a first surface integral with or part of a surface of a support on which the reagent pad is affixed thereto and in direct contact with an aperture has a reflectivity of less than about 12 percent at between about 600 and 730 nanometers.

As discussed above, Hirayama specifically shows and describes reflectance value for a cover 5 separately mounted over the reagent layer 3 and therefore fails to teach or suggest the claimed reflectance and frequency range for an area integral to the support surface 1 on which the reagent layer 3 is attached thereto and in direct contact with an aperture.

Notwithstanding the deficiency of Hirayama, Phillips fails to cure the deficiency of Hirayama by the proposed combination of references. While Phillips discusses that a reflectance of a porous matrix on which a reagent is provided thereon as being at least 25% and preferably

50% of the incident light emitted to the matrix (col. 6, lines 12-20), Phillips is silent as to a reflectance and range of frequency for a support. Consequently, it is respectfully submitted that one skilled in the art would not look to Phillips to cure the deficiencies of Hirayama to render the invention obvious. Accordingly, claim 5 is patentable over Hirayama and Phillips for at least this reason.

Applicants further submit that each of the relied-upon references, whether considered alone or in combination thereof, fails to teach or suggest all of the claimed features for a *prima facie* case of obviousness as set forth in MPEP § 2143. That is, even if Phillips could modify Hirayama, the relied-upon references fail to teach or suggest a device with a reflectance value over a range of light frequencies at a portion of a support integral with the surface on which a reagent pad is affixed thereon and in direct contact with an aperture. Hirayama shows and describes reflectance parameters for a cover rather than a support on which a reagent layer is attached thereto. Phillips is silent as to reflectance parameters of a support on which a reagent pad is attached thereto. Absent the benefit of applicants' own disclosure, there is no suggestion or motivation in the cited-upon prior art to modify the respective devices of Hirayama or Phillips in an attempt to provide for all of the claimed features of the claimed invention as a whole. Accordingly, claim 5 is patentable over the relied-upon references.

Finally, because Phillips fails to cure the deficiency of Hirayama with regard to respective independent claims 1, 5, and 10 on which dependent claims 3, 4, 6-9, 11 and 12 depend therefrom, claims 3, 4, 6-9, 11 and 12 are also patentable over the proposed combination of references, as well as for reciting other features.

Applicants respectfully request entry of the amendment as the amendment places the application in condition or in better form for appeal. No new matter would be raised by entry of this amendment because the amendment incorporates the Examiner's suggestions, addresses the Examiner's comments, and entry of the amendment would place the application in condition for allowance. Accordingly, applicants respectfully request entry, consideration and prompt allowance of the application.

## CONCLUSION

Applicants respectfully request that, in light of the amendments and explanations above, the Examiner reconsider and withdraw his rejections. Applicants respectfully submit that the claims are in condition for allowance. In the event that minor claim amendments are necessary to meet formal requirements, Applicants invite the Examiner to telephone the undersigned so that issuance can be expedited.

The Commissioner is hereby authorized to charge any required fees due in connection with this submission, including petition and extension of time fees, and to credit any overpayment to Deposit Account No. 10-0750 (Docket No. LFS0123US/KQT) (Johnson & Johnson).

Respectfully submitted,

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